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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,434	04/16/2004	Joseph Levy	LEVY=18A	9886

1444 7590 10/14/2009

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,434	LEVY ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 23-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/799,251.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114 filed 07/30/09 and the Amendment and Applicant's Arguments/Remarks filed 07/28/09 is acknowledged.

Claims 19 and 23-26 are pending in this action. Claim 19 has been amended. New claims 23-26 have been added. Claims 1-18 and 20-22 have been cancelled. Claims 19 and 23-26 are rejected.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 July 2009 has been entered.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19 and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A review of the instant specification establishes that support cannot be found for the newly added limitation of (said dosage form) "having as active ingredients only at least one phytoestrogen and at least one carotenoid" as presently recited in independent claim 19. Thus, this limitation introduces new matter into the claims. A review of the instant specification demonstrates that while support is provided for "a composition comprising a physiologically effective amount of at least one phytoestrogen and at least one carotenoid" on page 12, 2nd paragraph of the application specification, ample support has not been provided for a composition "*having as active ingredients only at least one phytoestrogen and at least one carotenoid*" as now claimed. Nowhere in the instant specification has support been located for the requirement that the "at least one phytoestrogen" and the "at least one carotenoid" be the only active ingredients present in the composition. Note that Applicant's themselves permitted the use of additional active ingredients such as the additional hormones as shown on p. 12, lower half of 2nd paragraph. Hence, ample support is lacking, based on the limitation "having as active ingredients only at least one phytoestrogen and at least one carotenoid". Consequently, this limitation introduces new matter into the claims.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson *et al.* (hereafter "Jackson") (U.S. Pat. No. 5,807,586).

Jackson ('586) teaches a dietary supplement composition and method for supplementing the dietary needs of a women comprising once daily administration of a composition comprising a physiologically effective amount of phytoestrogens in combination with mixed carotenoids having non-provitamin A activity, such as lycopene and lutein (see reference column 1, lines 4-10); (col. 4, line 39 – col. 5, line 14); (col. 6, line 63 – col. 7, line 25) and Table 1 at column 10. The teaching of "lutein" meets the Markush grouping of claim 23.

The dietary supplements are formulated to *reduce the risk factors of disease*, such as iron deficiency anemia, high cholesterol and CHD, oseteoporosis and some cancers during the

various life stages of a woman (col. 7, lines 25-35). The intake of the carotenoid, lycopene, has also been inversely associated with the risk of cervical cancer (col. 7, lines 4-9). Jackson also teaches that in general, the risk of cancer increases with age. Thus, the antioxidants and phytoestrogens appear to have a role in the prevention of some cancers, particularly breast cancer (col. 1, lines 40-45). At column 9, Jackson also states that the amount of phytoestrogens contributes to the reduction of some forms of cancer and is therefore increased in the composition for the second life stage (col. 9, lines 55-59). Thus, these teachings read on the "method for reducing the risk for developing cancer" as presently claimed by Applicant.

With regards to Applicant's limitation that the "carotenoid is substantially devoid of provitamin A activity", Jackson meets this limitation. Jackson teaches the inclusion of carotenoids having non-provitamin A activity, such as lycopene and lutein and thus teaches that types of carotenoids (with no provitamin A activity) are suitable for use in their composition (col. 7, lines 4-9). As a result, Jackson meets the limitation that the "carotenoid is substantially devoid of provitamin A activity", based on the teaching of lycopene and lutein, which are non-provitamin A (*i.e.*, non-retinol) carotenoids.

Regarding the claim limitation of claim 19, that the dosage form is one "having as active ingredients only at least one phytoestrogen and at least one carotenoid", as noted above, this limitation introduces new matter into the claims and has not been amply supported. Moreover, while Jackson includes some additional elements in their composition, asides from the phytoestrogens and carotenoids, such as vitamins and minerals, a review of the instant specification demonstrates that Applicant's themselves permit the inclusion of additional active ingredients, in addition to the phytoestrogens and carotenoids, such as the additional hormones

as shown on p. 12, lower half of 2nd paragraph. Thus, it cannot be seen as to how the additional vitamins and minerals of Jackson would be adversary to the instant formulation, since Applicants explicitly permit the inclusion of additional actives in their formulation. No closed-ended (i.e., "consisting of") claim language has been presented which would exclude the additional vitamins and minerals of Jackson. Consequently, Jackson remains relevant for its teachings.

The dietary supplements may be formulated as a tablet, capsule, powder, gel or liquid, or dietary bar and are preferably formulated for once daily administration (col. 3, lines 22-26). The phytoestrogens may be administered at levels of less than 25 mg per day (col. 5, lines 6-14).

With regards to the amount of carotenoid claimed, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Moreover, it is deemed to one of ordinary skill in the art to determine suitable ranges, percentages or ratios through routine or manipulative experimentation, to obtain the best possible results, as these are variable parameters attainable within the art. Furthermore, no unexpected or superior results have been observed in the instant amounts of carotenoid claimed (of about 2 mg or amount sufficient to cause effective serum concentration of the carotenoid of up to about 1.5 microM). The prior art clearly teaches a formulation having the same ingredients (phytoestrogens/carotenoids), whereby the formulation is effective to reduce the risk factors for various diseases, including some cancers. Jackson teaches the concept of providing a dietary supplement composition having a combination of phytoestrogens with mixed

carotenoids to combat diseases such as cancer. Hence, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Jackson.

* * * * *

Claims 19 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson *et al.* (hereafter "Jackson") (U.S. Pat. No. 5,807,586) in view of Schlipalius (U.S. Pat. No. 6,132,790).

The teachings of Jackson are discussed above.

Jackson does not teach a mixture of the various combinations of lycopene, phytoene and phytofluene as in present claims 24-26.

Schlipalius ('790) teaches a carotenoid composition comprising carotenoids that include lycopene, phytoene, phytofluene and mixtures thereof (see col. 3, lines 10-19) and claim 10. The carotenoid composition is derived from natural resources to result in a natural carotenoid composition (col. 1, lines 10-13). Lutein is also disclosed amongst suitable carotenoids (col. 3, line 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a mixture of carotenoids, such as a mixture of lycopene, phytoene and phytofluene as taught by Schlipalius within the formulations of Jackson. One would do so with a reasonable expectation of success because Schlipalius teaches a formulation mixture of carotenoids (*i.e.*, lycopene, phytoene and phytofluene), which, as evidenced by Jackson, are known to provide beneficial antioxidant activity and reduce the risk factors of various diseases,

such as cancers, based on the use of carotenoids. The expected result would be an effective method for reducing the risk potential for acquiring diseases (i.e., cancers).

* * * * *

Response to Arguments

Applicant's arguments filed 28 July 2009 have been fully considered but were not found to be persuasive.

- **35 U.S.C. §103(a) rejection over Jackson et al. (US '586) in view of Schlipalius (US '790):**

Applicant argued, "Jackson teaches the use of carotenoids having provitamin A activity. Jackson teaches away from using a composition having a carotenoid that is substantially devoid of provitamin A activity".

This argument has been fully considered but was not persuasive. With regards to Applicant's limitation that the "carotenoid is substantially devoid of provitamin A activity", Jackson meets this limitation. Jackson explicitly teaches the inclusion of carotenoids having non-provitamin A activity, such as lycopene and lutein and thus teaches that types of carotenoids (with no provitamin A activity) are suitable for use in their composition (col. 7, lines 4-9). As a result, Jackson meets the limitation that the "carotenoid is substantially devoid of provitamin A activity", based on the teaching of lycopene and lutein, which are non-provitamin A (*i.e.*, non-retinol) carotenoids. The mere teaching of including lycopene and lutein by Jackson is sufficient to meet the claim requirement of a carotenoid that is "substantially devoid of provitamin A activity". The art vividly recognizes and teaches the use of such carotenoids (i.e., lutein, lycopene) in combination with phytoestrogens and teaches the beneficial effects exhibited

thereby. While the amount of carotenoid is not disclosed by Jackson, it is the position of the Examiner that determination of suitable or effective amounts are within the level of the skilled artisan.

Applicant argued "Schlipalius has nothing to do with and cannot counteract the requirement of Jackson for the need for a certain minimum retinol activity. The '790 Patent does not relate to a method for reducing the risk for developing cancer during HRT and does not relate to compositions combining phytoestrogens and carotenoids or to provitamin A activity of the carotenoids."

The Examiner was not persuaded by this argument. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the secondary reference of Schlipalius amply resolves the deficiency of Jackson and was relied upon for the teaching that it is well known in the art to employ a combination of or a mixture of carotenoids. Schlipalius vividly teaches a carotenoid composition comprising the same carotenoids claimed by Applicant - namely, lycopene, phytoene and phytofluene and mixtures thereof (see col. 3, lines 10-19 of Schlipalius). Hence, the composition of Schlipalius would also provide for beneficial results, based on inclusion of the same components, absent a showing of evidence to the contrary.

Applicant argues that the "790 Patent does not relate to a method for reducing the risk for developing cancer during HRT". While it is noted that Schlipalius does not discuss the potential benefits of the carotenoids, note in particular, that the primary reference of Jackson initially teaches and evidences that the inclusion of non-provitamin A activity carotenoids, such as lycopene, are known to reduce the risk of certain cancers, such as cervical cancer (col. 7, lines 4-9). Thus, there is a direct correlation between intake of carotenoids and its' effect on diseases. One of ordinary skill in the art reading the teachings of Jackson would conclude that carotenoids are effective in reducing the potential risks of diseases, particularly cancers. Thus, one would also presume that the composition of Schlipalius, which comprises a mixture of carotenoids (having non-provitamin A activity) would also be exceptionally beneficial for reducing the risk factors for disease (i.e. cancers), based on Jackson who demonstrates the positive effects exhibited by carotenoids on diseases.

Applicant's argument that "Schlipalius has nothing to do with and cannot counteract the requirement of Jackson for the need for a certain minimum retinol activity" was not deemed convincing. As delineated above, Jackson explicitly teaches carotenoids having non-provitamin A activity, such as lycopene and lutein. Applicant is emphasizing the suggestion by Jackson of the use of carotenoids having retinol activity but is not highlighting the fact that Jackson also teaches carotenoids having non-provitamin A activity (lycopene/lutein) and thus, would meet Applicant's limitation of a carotenoid that is substantially devoid of provitamin A activity".

Lastly, Applicant expressed disagreement regarding the wording "substantially free of any other active component", which Applicant states, "means exactly that".

Applicant's arguments are noted. This limitation has been cancelled. However, the Examiner points out that the claim language now presented on the basis of excluding other actives/components has been accorded new matter. Namely, regarding the claim limitation of claim 19, that the dosage form is one "having as active ingredients only at least one phytoestrogen and at least one carotenoid", this limitation introduces new matter into the claims since it has not been amply supported by the present specification. The Examiner fails to find support for the limitation now presented by Applicant. Note in particular that Applicants themselves permit the use of additional active ingredients such as the additional hormones as shown on p. 12, lower half of 2nd paragraph.

The rejections of record have been maintained.

* * * * *

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

October 12, 2009